

Express Mail Label No. EL209599009US
U.S. National Phase Entry of PCT/GB00/01118
"Polycationic Carbohydrates as Immunostimulants in Vaccines"
Filed: 20 September 2001
PRELIMINARY AMENDMENT

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- (i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;
- (ii) a first material capable of forming particles; and
- (iii) a polycationic carbohydrate according to claim 1.

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10. (Amended) A composition according to claim 9 wherein the chitin derivative is chitosan, chitosan chloride, or chitosan glutamate or a polycationic carbohydrate according to claim 2.

11. (Amended) A composition according to claim 6 wherein the particle comprises microspheres, microparticles or liposomes.

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13. (Amended) A composition according to claim 6 wherein the first material is a polymeric material which has a molecular weight of 100kDa or more.

14. (Amended) A composition according to claim 6 wherein the first material comprises poly-(L-lactide).

15. (Amended) A composition according to claim 6 wherein the ratio of the first material to the polycationic carbohydrate is from 99:1 to 9:1 w/w.

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16. (Amended) A composition according to claim 6 wherein the biologically active agent is capable of generating a protective immune response against tetanus, diphtheria, or *Yersinia pestis*.

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18. (Amended) A composition according to claim 6 which is adapted for intranasal application.

19. (Amended) A composition according to claim 6 which is adapted for parenteral administration.

20. (Amended) A composition according to claim 6 which further comprises a chemical compound selected from

- (A) a polyamino acid,
- (B) a vitamin or vitamin derivative,
- (C) cationic pluronics,
- (D) a clathrate,
- (E) a complexing agent,
- (F) cetrimides,
- (G) an S-layer protein, or
- (H) methyl-glucamine.

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23. (Amended) A method for producing a pharmaceutical composition, which method comprises encapsulating a biologically active agent in a first material, in the presence of a polycationic carbohydrate according to claim 1.

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30. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate according to claim 1.

31. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, in the form of a composition according to claim 6.

32. (Amended) A method according to claim 30 wherein the protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate is applied parenterally or to a mucosal surface.

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35. (Amended) The use of a polycationic carbohydrate or a pharmaceutically acceptable derivative thereof according to claim 1 as an immunostimulant, in the preparation of a vaccine for use in prophylactic or therapeutic treatment.

Respectfully submitted,



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